510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter's information

Name: Andon Medical Co., Ltd.
Address: No.26 Hangn Yu Road, Tianjin Airport Economic Area, Tianjin, P.R. China
Phone number: 86-22-8761 2426
Fax number: 86-22-6052 6162
Contact: Yi Liu
Date of Application: 12/30/2010

2.0 Device information

Trade name: AG-608N Single Blood Glucose Monitoring System
AG-608N Multi Blood Glucose Monitoring System
Common name: Blood Glucose Monitoring System
Classification name: Blood Glucose Monitoring System

3.0 Classification

Production code: NBW- Blood Glucose Monitoring System.
Regulation number: 862.1345
Classification: II
Panel: Clinical Chemistry

4.0 Predict device information

Manufacturer: Andon Medical Co., Ltd.
Device: AG-608 Blood Glucose Monitoring System
510(k) number: k093262

5.0 Device description

AG-608N Single Blood Glucose Monitoring System and AG-608N MULTI Blood Glucose Monitoring System measures the amount of sugar (glucose)

in whole blood. The glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. Your meter measures the current, calculates the blood glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

6.0 Intended use

6.1 AG-608N Single BGMS

The AG-608N single Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh. The AG-608N single Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The AG-608N single Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The AG-608N single Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The AGS-1000N single Test Strips are for use with the AG-608N single Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The AG-608N control solutions are intended for use with the AG-608N single Blood Glucose Monitoring System, to check that the glucose meter and test strips are working properly and that you are doing the test correctly. These solutions contain a known range of glucose, as indicated on the bottles.

6.2 AG-608N MULTI BGMS

The AG-608N MULTI Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh. The AG-608N MULTI Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an

aid to monitor the effectiveness of diabetes control program. The system is only used with single-use lancing devices.

The AG-608N MULTI Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, upper arm, calf and thigh should be done only during steady – state times (when glucose is not changing rapidly).

The AGS-1000N MULTI Test Strips are for use with the AG-608N MULTI Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and.thigh.

The AG-608N control solutions are intended for use with the AG-608N MULTI Blood Glucose Monitoring System, to check that the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

7.0 Summary comparing technological characteristics with predicate device

Similarities		
CHARACTERISTICS	**NEW DEVICE: AG-608N Single and MULTI Blood Glucose Monitoring System**	**PREDICATE: AG-608 Blood Glucose Monitoring System** (K093262)
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase
Type of Meter	Biosensor (Electrode)	Biosensor (Electrode)
Sample Source	Capillary whole blood from AST(Alternative site testing) and finger	Capillary whole blood from finger
Sample Application	Blood sample is placed directly to the test strip after finger or AST is lanced.	Blood sample is placed directly to the test strip after finger is lanced.
Hematocrit Range	20-60%	35-50%
Altitude	10744 feet(3275m)	11975 feet(3650m)
Operating Temperature Range	10℃～40℃(50°-104°F)	10℃～40℃(50°-104°F)
Dimensions	87mmx 53mmx 9.9mm	85mm×53mm(W)×13.7mm (H)

Display	LCD	LCD
Result Presentation	mg/dL or mmol/L	mg/dL or mmol/L
Memory Capabilities	500 times with time and date displaying	350 times with time and date displaying
Test Start	Automatic	Automatic
Test Time	5 second	5 second
Power Source	DC 3V (CR2032)	DC 3V (CR2032)
Battery Life	Approx. 500 normal tests	Approx. 1000 normal tests
Measurement Range	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)
Qualified Test Strip	AGS-1000N Test Strip	AGS-1000 Test Strip
Sample Volume	Minimum 0.7 micro liter	Minimum 0.7 micro liter
Other function	USB function.	N/A

8.0 Performance summary

AG-608N Single and AG-608N MULTI blood glucose monitoring system conforms to the following standards:

- ISO 15197: In vitro diagnostic test systems- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

Non-clinical test and the clinical test are done according to the above standard.

9.0 Comparison to the predict device and the conclusion

AG-608N Single and AG-608N MULTI are similar with the predicate device AG-608, however, the appearance is different from AG-608, it uses the different test strips, AG-608N Single and AG-608N MULTI can test the blood glucose at the alternative site other than the finger, it also has the USB function. The hematocrit range is different, the altitude, the memory capability, the Battery Life are also changed. AG-608N Single and AG-608N MULTI also has a USB function.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JAN 18 2012

Andon Medical Co, Ltd
c/o Yi Liu
No. 04-23-3 Airport Industrial
Park, Tianjin
Tianjin
China 300381

Re: k110017
Trade Name: AG-608N MULTI Blood Glucose Monitoring System,
AG-608N single Blood Glucose Monitoring System
Regulation Number: 21 CFR §866.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: December 19, 2011
Received: December 19, 2011

Dear Yi Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: AG-608N Single Blood Glucose Monitoring System

Indication For Use:
The AG-608N Single Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh. The AG-608N single Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The AG-608N single Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The AG-608N single Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The AGS-1000N single Test Strips are for use with the AG-608N single Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The AG-608N control solutions are intended for use with the AG-608N single Blood Glucose Monitoring System, to check that the glucose meter and test strips are working properly and that you are doing the test correctly. These solutions contain a known range of glucose, as indicated on the bottles.

Prescription Use √	And/Or	Over the Counter Use √
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110017

Indication for Use

510(k) Number (if known):

Device Name: AG-608N MULTI Blood Glucose Monitoring System

Indication For Use:
The AG-608N MULTI Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh. The AG-608N MULTI Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. The system is only used with single-use lancing devices.

The AG-608N MULTI Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, upper arm, calf and thigh should be done only during steady – state times (when glucose is not changing rapidly).

The AGS-1000N MULTI Test Strips are for use with the AG-608N MULTI Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The AG-608N control solutions are intended for use with the AG-608N MULTI Blood Glucose Monitoring System, to check that the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

Prescription Use √	And/Or	Over the Counter Use √
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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